IAP6 Rec'd PCT/PTO 2.9

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TRANSMITTAL LETTER TO THE UNITED STATES **DESIGNATED/ELECTED OFFICE (DO/EO/US)**

ATTORNEY'S DOCKET NUMBER

AM100240

U.S. APPLICATION NO. (If known, see 37 CFR 1.5) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371 PRIORITY DATES OF ALMED INTERNATIONAL APPLICATION NO. INTERNATIONAL FILING DATE PCT/US2004/043792 28 December 2004 30 December 2003 TITLE OF INVENTION Formulations of Hydrophobic Proteins in an Immunogenic Composition Having Improved APPLICANT(S) FOR DO/EO/US Tolerability Susan Kay Hoiseth, et al. Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information: This is a FIRST submission of items concerning a submission under 35 U.S.C. 371. This is a SECOND or SUBSEQUENT submission of items concerning a submission under 35 U.S.C. 371. This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below. The US has been elected (Article 31). A copy of the International Application as filed (35 U.S.C. 371(c)(2)) is attached hereto (required only if not communicated by the International Bureau). X has been communicated by the International Bureau. is not required, as the application was filed in the United States Receiving Office (RO/US). An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)). is attached hereto. has been previously submitted under 35 U.S.C. 154(d)(4). 7 X Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) are attached hereto (required only if not communicated by the International Bureau). have been communicated by the International Bureau. have not been made; however, the time limit for making such amendments has NOT expired. have not been made and will not be made. An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). 10. An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)). Items 11 to 20 below concern document(s) or information included: 11. X An Information Disclosure Statement under 37 CFR 1.97 and 1.98. An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. 13. X A preliminary amendment. An Application Data Sheet under 37 CFR 1.76. A substitute specification. A power of attorney and/or change of address letter. A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821-1.825. A second copy of the published International Application under 35 U.S.C. 154(d)(4). A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).

This collection of information is required by 37 CFR 1.414 and 1.491-1.492. The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 15 minutes to complete, including gathering information, preparing, and submitting the completed form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450. Page 1 of 3

IAP20 Rec'd PCT/PTO 29 JUN 2006

PTO-1390 (Rev. 07-2005)
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JONNS (815050 BR 1.5) INTERNATIONAL APPLICATION NO. ATTORNEY'S DOCKET NUMBER PCT/US2004/043792 AM100240 Form PTO-1449 20. Other items or information: References The following fees have been submitted **CALCULATIONS** PTO USE ONLY 21. 300.00 Examination fee (37 CFR 1.492(c)) \$ If the written opinion prepared by ISA/US or the international preliminary examination report prepared All other situations.....\$200 200.00 23. X Search fee (37 CFR 1.492(b)) If the written opinion of the ISA/US or the International preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)..... Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an previously communicated to the US by the IB......\$400 400.00 All other situations......\$500 900.00 TOTAL OF 21, 22 and 23 = Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(j)). The fee is \$250 for each additional 50 sheets of paper or fraction thereof. **Total Sheets** Extra Sheets Number of each additional 50 or fraction RATE thereof (round up to a whole number) 0.00 - 100 = /50 = x \$250 Surcharge of \$130.00 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)). RATE \$ CLAIMS NUMBER FILED NUMBER EXTRA Total claims 36 - 20 =\$ 50 \$ 800.00 16 Independent claims - 3 = 3 \$200 \$ 600.00 х MULTIPLE DEPENDENT CLAIM(S) (if applicable) \$360 TOTAL OF ABOVE CALCULATIONS = \$1,400.00 Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2. \$2,300.00 Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)). **TOTAL NATIONAL FEE =** \$2,300.00 Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property TOTAL FEES ENCLOSED = \$2,300.00 Amount to be \$ refunded: Amount to be \$2,300.00 charged

10/585050

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| \overline{A} | A check in the amount of \$ to coverating about 199 JUN 2006 |
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|). X | Please charge my Deposit Account No. $01-1425$ in the amount of \$2,300.00 to cover the above fees. A duplicate copy of this sheet is enclosed. |
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| NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status. | |
| Wyet Pate Five Madi | SIGNATURE Darrell Fontenot, Ph.D. Right Law Department Giralda Farms Son, NJ 07940 No. (845) 602-3144 SIGNATURE Darrell Fontenot, Ph.D. REGISTRATION NUMBER |

10/585050 Expland RCT (DLO 2:325) 2006

June 29, 2006

Mail Stop PCT Commissioner for Patents PO Box 1450 · Alexandria, VA 22313-1450

Re:

National Stage of PCT Application No. PCT/US2004/043792

Title:

FORMULATIONS OF HYDROPHOBIC PROTEINS IN AN

IMMUNOGENIC COMPOSITION HAVING IMPROVED

TOLERABILITY

Filed:

December 28, 2004

Inventor(s): Susan Kay Hoiseth, et al.

Our Ref:

AM100240

Sir:

We enclose the following papers for entering the national stage in the USPTO for the above-captioned PCT application:

Transmittal Letter (Form PTO-1390)
Application Data Sheet
WO 2005/065708 A2
Preliminary Amendment
Combined Declaration and Power of Attorney
Information Disclosure Statement
PTO 1449
References

Correspondence Address: Customer Number: 25291

Respectfully submitted,

By: Darrell Fontenot, Ph.D. Attorney for Applicants

Reg. No. 46,705

Wyeth Patent Law Department Five Giralda Farms Madison, NJ 07940 Tel. No. (845) 602-3144

CERTIFICATE OF MAILING 37 CFR §1.10

I hereby certify that this paper and the documents referred to as enclosed therein are being deposited with the United States Postal Service on the date written below in an envelope as "Express Mail Post Office to Addressee" Mailing Label Number ED451929250US addressed to the Mail Stop PCT, Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450.

June 29, 2006

Ann Peterson